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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

In re Application of :
Robl, et al. : DECISION ON APPLICATION
Application No. 09/988,115 : FOR PATENT TERM ADJUSTMENT
Filed: November 16, 2001 :
Atty. Dkt. No: 50195/008003 :
:

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT
37 C.F.R. § 1.705" filed November 4, 2005.

The application for patent term adjustment ("PTA") under 37 CFR
1.705(b) is hereby **DISMISSED**.

The correct PTA at the time of the allowance is zero days as
indicated on the Determination of Patent Term Adjustment under
35 U.S.C. 154(b) mailed October 21, 2005.

The Determination of Patent Term Adjustment under 35 U.S.C.
154(b) in the above-identified application, mailed October 21,
2005, indicated that the PTA to date is zero days. The instant
application for patent term adjustment was timely filed November
4, 2005. Applicants request that the PTA be corrected from zero
days to reflect an adjustment of 59 days. Applicants acknowledge
that as of the time of allowance, an adjustment of 260 days can
be attributed to the Office. Applicants, however, argue that
applicants' delay totals 201 days rather than 323 days.

Applicants have acknowledged the following reductions as true
and correct: 16 days under 37 CFR 1.704(b) in connection with
the response submitted August 5, 2005; and, 94 days under 37 CFR
1.704(b) in connection with the response submitted January 31,
2005.

Further reductions are required as detailed herein.

The adjustment of 260 days is further reduced 94 days in
accordance with 37 CFR 1.704(b) in connection with the response
submitted June 6, 2002 in response to the Notice of File Missing
Parts mailed December 4, 2001. The reduction began March 5,
2002, the day after the date that is three months after the date

that the Notice to File Missing Parts was mailed, and ended June 6, 2006, the date of receipt of the response thereto.

It is noted that applicants in this regard acknowledge a reduction of 91 days, stating that the response was submitted June 3, 2002. It is noted that the response bears a certificate of mailing date of June 3, 2002, however, the response is date stamped as received in the USPTO on June 6, 2002. The date indicated on any certificate of mailing or transmission under 1.8 shall not be taken into account in the instant calculation of PTA. See 37 CFR 1.704(f).

The adjustment is further reduced 61 days in accordance with 37 CFR 1.704(c)(7) in connection with the response submitted August 6, 2002. The reduction began June 7, 2002, the day after the date that the reply having an omission was filed, and ended August 6, 2002, the date that the reply or other paper correcting the omission was filed.

Applicants have argued in this regard that the Notice to Comply with Sequence Listing Requirements, mailed June 24, 2002, indicated that applicants' diskette was "Damaged." Applicants further argue that this damage "likely resulted from security procedures at the PTO and was not the result of Applicant error or delay."

Applicants argument has been considered but is not found convincing. The Notice to Comply with Sequence Listing Requirements indicated that applicants' diskette was damaged and/or unreadable. There is no indication in the official record that any damage to the disk or unreadability of the disk is attributable to any action or inaction on the part of the Office. Accordingly, the submission of the reply on August 6, 2002 is deemed a failure to engage in reasonable efforts to conclude prosecution within the meaning of 37 CFR 1.704(c)(7).

The adjustment of 260 days is further reduced 58 days in accordance with 37 CFR 1.704(c)(8) in connection with the Information Disclosure Statement (IDS) submitted June 9, 2004. The reduction began April 13, 2004, the day after the date a response to the election/restriction requirement was filed, and ended June 9, 2004, the date the IDS was filed.

Applicants have argued that the submission of the IDS was timely filed and was not submitted either less than one month before the mailing of an Office Action, after the filing of a

substantive reply, after a decision by the Board of Appeals, or after a Notice of Allowance in accordance with 37 CFR 1.704(d).

In accordance with 37 CFR 1.704(c)(8), submission of a supplemental reply or other paper, i.e., IDS, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed is deemed a failure to engage in reasonable effort to conclude prosecution.

Moreover, a written restriction requirement, a written election of species requirement, a requirement for information under 37 CFR 1.105, an action under Ex parte Quayle, 1935 Comm'r Dec. 11 (1935), and a notice of allowability (PTOL-37) are each an action issued as a result of the examination conducted pursuant to 35 U.S.C. 131. See MPEP 2731.

A reply to the election/restriction requirement was filed April 12, 2004. The IDS was filed thereafter on June 9, 2004. Accordingly, submission of the IDS is deemed a failure to engage in reasonable efforts to conclude prosecution within the meaning of 37 CFR 1.704(c)(8).

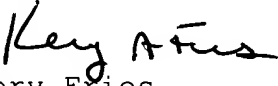
Accordingly, at the time of allowance, the application is entitled to an adjustment of zero days, as indicated in the Notice of Allowance mailed October 21, 2005.

The Office acknowledges receipt of the required \$200.00 application fee.

The patent term adjustment indicated in the patent will include any additional patent term accrued pursuant to §§ 1.702(a)(4) and 1.702(b).

The application is being forwarded to the Publications Division for issuance of a patent.

Telephone inquiries specific to this matter should be directed to Petitions Attorney Alesia M. Brown at (571) 272-3205.


Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of Deputy Commissioner
for Patent Examination Policy

Date Calculator Result

From 06/06/2002 to 08/06/2002 is 61 days.

New calculation

Date Calculator Result

From 03/04/2002 to 06/06/2002 is 94 days.

New calculation



PATENT
ATTORNEY DOCKET NO. 50195/008003

Certificate of Mailing: Date of Deposit: November 1, 2005

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Colleen Coyne
Printed name of person mailing correspondence

Colleen Coyne
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James M. Robl et al. Art Unit: 1632
Serial No.: 09/988,115 Examiner: D. Crouch
Filed: November 16, 2001 Customer No.: 21559
Title: TRANSGENIC BOVINE COMPRISING HUMAN
IMMUNOGLOBULIN LOCI AND PRODUCING HUMAN
IMMUNOGLOBULIN

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Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) set forth on the Issue Notification mailed on October 21, 2005 in connection with the above-captioned patent application, Applicants hereby request reconsideration of the patent term adjustment. Applicants submit that the current patent term adjustment should be 59 days (i.e., a 260 day period of Patent Office delay reduced by a 201 day period of Applicant delay as detailed below).

In support of this application, Applicants first summarize crucial dates and actions

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that resulted in patent term adjustment. The present application was filed on November 16, 2001 and the first action under 35 U.S.C. § 132, a Restriction Requirement, was not mailed until September 11, 2003. The mailing of the restriction requirement was 238 days later than fourteen months from the filing date of the application, resulting in 238 days of patent term adjustment. 37 CFR 1.703(a)(1). A second Restriction Requirement was then mailed March 9, 2004, 22 days later than the four month period allowed for a subsequent PTO Action. 37 CFR 1.703(a)(2). The total Office delay was therefore 260 days, as correctly indicated by PAIR (copy enclosed).

Applicant delay occurred in connection with three submissions. A Reply to a non-final Office Action of July 29, 2004 was submitted on January 31, 2005, a delay of 94 days. A Reply to a final Office Action of April 20, 2005 was submitted on August 5, 2005, a delay of 16 days. And a Reply to Notice of Missing Parts of December 4, 2001 was submitted on June 3, 2002, a delay of 91 days, resulting in a total Applicant delay of 201 days.

It is the calculation of Applicant delay by the PTO with which Applicants disagree. As indicated on the accompanying PAIR summary, the Office has assessed a delay of 155 days for Applicants' Reply to the Notice of Missing Parts mailed December 4, 2001. This calculation is in error. The Notice of Missing Parts mailed December 4, 2001 required the submission of a sequence listing, executed inventor declarations, and substitute drawings. The executed declarations and substitute drawings were submitted

on June 3, 2002 and account for a 91 day Applicant delay. The remaining submission, the sequence listing, was mailed by Applicants on February 7, 2002 and date-stamped as received by the PTO on March 11, 2002. A copy of the date-stamped postcard is enclosed; PAIR does not indicate receipt of this submission. On June 24, 2002, the Office mailed a further Notice to Comply with Sequence Listing Requirements, indicating that Applicants' sequence diskette was "Damaged." Given the timing of this submission, this damage likely resulted from security procedures at the PTO and was not the result of Applicant error or delay. Also, the indication in PAIR that this mailing was due to "SEQUENCE ERRORS" is incorrect, as the Office required a new submission solely due to the damaged diskette. As Applicants provided a new diskette on August 6, 2002, no Applicant delay should be assessed in connection with any of the sequence listing submissions. The PAIR indication of 155 days of Applicant delay in connection with the Reply to Notice to File Missing Parts is in error and should instead be 91 days.

In addition, the Office has assessed a 58 day period of Applicant delay in connection with the filing of an Information Disclosure Statement on June 9, 2004. This assessment of Applicant delay is also in error, as this IDS was timely filed and was not submitted either less than one month before the mailing of an Office Action (which occurred on July 29, 2004), after the filing of a substantive reply (which occurred on January 31, 2005), after a decision by the Board of Appeals, or after a notice of allowance (which occurred on October 21, 2005). 37 CFR 1.704(d). It appears that the Office may

have inadvertently confused Applicants' Reply to the second Restriction Requirement with a Reply to a first substantive Office Action. This assessment of 58 days of Applicant delay should be withdrawn.

In addition, Applicants note that the present patent is not subject to a Terminal Disclaimer.

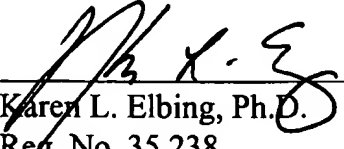
CONCLUSION

Applicants submit that the current patent term adjustment should be 59 days and request reconsideration of the patent term adjustment.

Enclosed is a check in the amount of \$200.00 for the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 01 November 2005



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